

117TH CONGRESS
2D SESSION

H. R. 7253

To amend the Federal Food, Drug, and Cosmetic Act to provide for clarification of requirements for the remanufacturing of medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 28, 2022

Mr. PETERS (for himself, Mr. JOYCE of Pennsylvania, and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for clarification of requirements for the remanufacturing of medical devices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Clarifying Remanufac-
5 turing to Protect Patient Safety Act of 2022”.

6 **SEC. 2. CLARIFICATION OF REMANUFACTURING IN DEFINI-**
7 **TION.**

8 Section 510 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 360) is amended—

1 (1) by subsection (a), by amending paragraph
2 (1) to read as follows:

3 “(1) The term ‘manufacture, preparation, prop-
4 agation, compounding, or processing’ shall include
5 the following:

6 “(A) Repackaging or otherwise changing
7 the container, wrapper, or labeling of any drug
8 package or device package in furtherance of the
9 distribution of the drug or device from the
10 original place of manufacture to the person who
11 makes final delivery or sale to the ultimate con-
12 sumer or user.

13 “(B) Remanufacturing of any finished de-
14 vice by engaging in any act that could signifi-
15 cantly change the performance or safety speci-
16 fications, or intended use, of the finished device,
17 including by significantly changing—

18 “(i) a sterilization method;

19 “(ii) a reprocessing instruction;

20 “(iii) a control mechanism, operating
21 principle, or energy input or output;

22 “(iv) the anatomical location of use;

23 or

24 “(v) the design.”; and

1 (2) in subsection (j), by adding at the end the
2 following:

3 “(6) The Secretary shall require that lists of devices
4 reported pursuant to paragraph (2) specifically identify in
5 any such list those devices that have been or are being
6 remanufactured as described in subsection (a)(1)(B).”.

7 **SEC. 3. INSPECTION OF DEVICE REMANUFACTURING ES-**
8 **TABLISHMENTS.**

9 Section 510(h) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360(h)) is amended—

11 (1) in paragraph (4)—

12 (A) by redesignating subparagraph (H) as
13 subparagraph (G); and

14 (B) by inserting after subparagraph (F)
15 the following:

16 “(G) Whether the establishment is reg-
17 istered as a remanufacturer or otherwise be-
18 lieved to be engaged in remanufacturing.”; and

19 (2) in paragraph (6)(A)—

20 (A) in clause (i), by striking “and” at the
21 end;

22 (B) in clause (ii), by inserting “and” after
23 the semicolon; and

24 (C) by adding at the end the following:

1 “(iii) the number of establishments reg-
2 istered as remanufacturers that the Secretary
3 inspected in the previous calendar year;”.

4 **SEC. 4. DEVICE REMANUFACTURING PUBLIC EDUCATION.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services shall hold at least one public forum with-
7 in 12 months after the date of enactment of this Act, and
8 shall take other ongoing steps as necessary, to increase
9 public awareness of the requirements applicable to device
10 remanufacturing, including—

11 (1) holding webinars; and
12 (2) engaging in other outreach to regulated in-
13 dustry, professional societies, advocacy groups, State
14 and local governmental entities, and other stake-
15 holders.

16 (b) REPORT.—

17 (1) IN GENERAL.—Not later than 2 years after
18 the date of enactment of this Act, the Secretary of
19 Health and Human Services shall—

20 (A) prepare and post on the website of the
21 Food and Drug Administration a report with
22 regard to the remanufacturing of devices; and

23 (B) brief the Committee on Energy and
24 Commerce of the House of Representatives and
25 the Committee on Health, Education, Labor,

1 and Pensions of the Senate regarding the find-
2 ings of such report.

3 (2) CONTENTS.—The report under paragraph
4 (1) shall include the following:

5 (A) A description of the activities carried
6 out, and additional activities intended to be car-
7 ried out, under subsection (a).

8 (B) The number of remanufacturing estab-
9 lishment registrations and remanufactured de-
10 vice listings under section 510 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C.
12 360), and any trends in such registrations and
13 listings.

14 (C) An assessment of whether the Food
15 and Drug Administration should issue guidance
16 for remanufacturers on compliance with the es-
17 tablishment registration and device listing re-
18 quirements of such section 510.

19 (D) A summary of inspections carried out,
20 warning letters and other advisory actions, and
21 enforcement actions relating to remanufac-
22 turing establishments since the date of enact-
23 ment of this Act.

24 (E) The status of actions undertaken pur-
25 suant to the report issued by the Secretary pur-

1 suant to section 710 of the FDA Reauthoriza-
2 tion Act of 2017 (Public Law 115–52).

3 (3) ANNUAL UPDATES.—On an annual basis,
4 the Secretary of Health and Human Services shall—

5 (A) update the report required by this sub-
6 section with regard to the information described
7 in subparagraphs (B) and (D) of paragraph
8 (2); and

9 (B) post each such update on the website
10 of the Food and Drug Administration.

11 (c) DEFINITION.—In this section and section 5, the
12 term “device” has the meaning given to such term in sec-
13 tion 201 of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 321).

15 **SEC. 5. ENHANCED COMMUNICATIONS REGARDING RE-**
16 **MANUFACTURING.**

17 The Secretary shall implement a process, to be posted
18 on the website of the Food and Drug Administration, to
19 receive through the Food and Drug Administration sub-
20 missions from State regulatory bodies and other State au-
21 thorities—

22 (1) expressing concerns that an entity that is
23 remanufacturing devices—

1 (A) is not registered under section 510 of
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 360); or

4 (B) may otherwise be acting contrary to
5 the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 301 et seq.); and

7 (2) describing any actions taken by State au-
8 thorities against such entity.

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